

(*Ostertagia ostertagi*); barberpole worm (*Haemonchus contortus*, *H. placei*); small stomach worm (*Trichostrongylus axei*); adult and 4th stages larvae of intestinal worms (thread-necked intestinal worm (*Nematodirus spathiger*, *N. helvetianus*); small intestinal worm (*Cooperia punctata* and *C. oncophora*); adult stages of intestinal worms (hookworm (*Bunostomum phlebotomum*); bankrupt worm (*Trichostrongylus colubriformis*), nodular worm (*Oesophagostomum radiatum*); adult and 4th stage larvae of lungworms (*Dictyocaulus viviparus*).

(3) *Limitations*. Administer as a single oral dose. Do not slaughter within 27 days of last treatment. Do not use in female dairy cattle of breeding age. Do not administer to female cattle during first 45 days of pregnancy or for 45 days after removal of bulls. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

[54 FR 51385, Dec. 15, 1989, as amended at 56 FR 50653, Oct. 8, 1991; 60 FR 55658, Nov. 2, 1995]

§ 520.48 Altrenogest solution.

(a) *Specifications*. Each milliliter (mL) of solution contains 2.2 milligrams (mg) altrenogest.

(b) *Sponsor*. See No. 057926 in § 510.600(c) of this chapter.

(c) *Tolerances*. See § 556.36 of this chapter.

(d) *Conditions of use*—(1) *Horses*—(i) *Amount*. 1.0 mL per 110 pounds body weight (0.044 mg/kg) daily for 15 consecutive days.

(ii) *Indications for use*. For suppression of estrus in mares.

(iii) *Limitations*. For oral use in horses only; avoid contact with the skin. Do not administer to horses intended for use as food. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Swine*—(i) *Amount*. Administer 6.8 mL (15 mg altrenogest) per gilt once daily for 14 consecutive days by top-dressing on a portion of each gilt's daily feed.

(ii) *Indications for use*. For synchronization of estrus in sexually mature gilts that have had at least one estrous cycle.

(iii) *Limitations*. Do not use in gilts having a previous or current history of uterine inflammation (i.e., acute, subacute or chronic endometritis). Gilts must not be slaughtered for human consumption for 21 days after the last treatment.

[66 FR 47960, Sept. 17, 2001, as amended at 68 FR 62006, Oct. 31, 2003]

§ 520.62 Aminopentamide hydrogen sulphate tablets.

(a) *Chemical name*. 4-(Dimethylamino)-2,2-diphenylvaleramide hydrogen sulfate.

(b) *Specifications*. Each tablet contains 0.2 milligram of the drug.

(c) *Sponsor*. See No. 000856 in § 510.600(c) of this chapter.

(d) *Conditions of use*. (1) It is intended for use in dogs and cats only for the treatment of vomiting and/or diarrhea, nausea, acute abdominal visceral spasm, pylorospasm, or hypertrophic gastritis.

NOTE: Not for use in animals with glaucoma because of the occurrence of mydriasis.

(2) Dosage is administered by oral tablet every 8 to 12 hours, as follows:

Weight of animal in pounds	Dosage in milligrams
Up to 10	0.1
11 to 20	0.2
21 to 50	0.3
51 to 100	0.4
Over 100	0.5

Dosage may be gradually increased up to a maximum of five times the suggested dosage. Oral administration of tablets may be preceded by subcutaneous or intramuscular use of the injectable form of the drug.

(3) For use only by or on the order of a licensed veterinarian.

[40 FR 13838, Mar. 27, 1975, as amended at 53 FR 27851, July 25, 1988]

§ 520.82 Aminopropazine fumarate oral dosage forms.

§ 520.82a Aminopropazine fumarate tablets.

(a) *Specifications*. The drug is in tablet form. Each tablet contains aminopropazine fumarate equivalent to 25 milligrams of aminopropazine base.

§ 520.82b

(b) *Sponsor*. See No. 000061 in § 510.600(c) of this chapter.

(c) *Conditions of use*. (1) The drug is used in dogs and cats for reducing excessive smooth muscle contractions, such as occur in urethral spasms associated with urolithiasis.¹

(2) It is administered at a dosage level of 1 to 2 milligrams per pound of body weight. The dosage can be repeated every 12 hours, as indicated.¹

(3) Not for use in animals intended for food purposes.

(4) For use only by or on the order of a licensed veterinarian.¹

[40 FR 13838, Mar. 27, 1975, as amended at 46 FR 48642, Oct. 2, 1981; 61 FR 8873, Mar. 6, 1996; 62 FR 61624, Nov. 19, 1997]

§ 520.82b Aminopropazine fumarate, neomycin sulfate tablets.

(a) *Specifications*. The drug is in tablet form. Each tablet contains both aminopropazine fumarate equivalent to 25 milligrams of aminopropazine base and neomycin sulfate equivalent to 50 milligrams of neomycin base.

(b) *Sponsor*. See No. 000061 in § 510.600(c) of this chapter.

(c) *Conditions of use*. (1) The drug is used in dogs to control bacterial diarrhea caused by organisms susceptible to neomycin and to reduce smooth muscle contractions.¹

(2) It is administered at a dosage level of one to two tablets per 10 pounds of body weight twice daily for 3 days.¹

(3) Federal law restricts this drug to use by or on the order of a licensed veterinarian.¹

[40 FR 13838, Mar. 27, 1975, as amended at 46 FR 48642, Oct. 2, 1981; 61 FR 8873, Mar. 6, 1996; 62 FR 61624, Nov. 19, 1997]

§ 520.88 Amoxicillin oral dosage forms.

§ 520.88a Amoxicillin trihydrate film-coated tablets.

(a) *Specifications*. Each tablet contains amoxicillin trihydrate equivalent to 50, 100, 150, 200, or 400 milligrams of amoxicillin.

¹These conditions are NAS/NRC reviewed and deemed effective. Applications for these uses need not include effectiveness data as specified by § 514.111 of this chapter, but may require bioequivalency and safety information.

21 CFR Ch. I (4–1–05 Edition)

(b) *Sponsor*. See No. 000069 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Dogs*—(i) *Amount*. 5 milligrams per pound of body weight, twice a day.

(ii) *Indications for use*. Treatment of infections of the respiratory tract (tonsillitis, tracheobronchitis), genitourinary tract (cystitis), gastrointestinal tract (bacterial gastroenteritis), and soft tissues (abscesses, lacerations, wounds), caused by susceptible strains of *Staphylococcus aureus*, *Streptococcus* spp., *Escherichia coli*, *Proteus mirabilis*, and bacterial dermatitis caused by *S. aureus*, *Streptococcus* spp., and *P. mirabilis*.

(iii) *Limitations*. Administer for 5 to 7 days or 48 hours after all symptoms have subsided. If no improvement is seen in 5 days, review diagnosis and change therapy. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Cats*—(i) *Amount*. 50 milligrams (5 to 10 milligrams per pound of body weight) once a day.

(ii) *Indications for use*. Treatment of infections caused by susceptible organisms as follows: upper respiratory tract due to *S. aureus*, *Streptococcus* spp., and *E. coli*; genitourinary tract (cystitis) due to *S. aureus*, *Streptococcus* spp., *E. coli*, and *P. mirabilis*; gastrointestinal tract due to *E. coli*; and skin and soft tissue (abscesses, lacerations, and wounds) due to *S. aureus*, *Streptococcus* spp., *E. coli*, and *Pasteurella multocida*.

(iii) *Limitations*. Administer for 5 to 7 days or 48 hours after all symptoms have subsided. If no improvement is seen in 5 days, review diagnosis and change therapy. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37319, Aug. 18, 1992, as amended at 60 FR 55658, Nov. 2, 1995]

§ 520.88b Amoxicillin trihydrate for oral suspension.

(a) *Specifications*. When reconstituted, each milliliter contains amoxicillin trihydrate equivalent to 50 milligrams of amoxicillin.

(b) *Sponsor*. See No. 000069 in § 510.600(c) of this chapter.